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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/158,120	09/21/1998	LESLIE SID JOHNSON	RS100CP1D1	3563
36577	7590	02/09/2005	EXAMINER	
JOHNATHAN KLEIN-EVANS ONE MEDIMMUNE WAY GAITHERSBURG, MD 20878			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/158,120

Applicant(s)

JOHNSON, LESLIE SID

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-64 is/are pending in the application.
- 4a) Of the above claim(s) 59-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is responsive to paper filed 19 October 2004.

Newly submitted claims 59-64 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The above referenced claims are directed to methods of using RSV antibodies which were restricted from the elected composition. See paper #9, mailed September 21, 1998. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 59-64 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03.

This action is on claims 35- 58.

Rejections Maintained

Claim Rejections - 35 USC # 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23- 25, 26- 29, and 31- 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones *et al.* in view of Beeler *et al.*

Applicant argues that there is no motivation to combine the references, that the references do not combine to make a protective antibody, that it was well known in the art that in vitro neutralization does not correlate to in vivo neutralization and cites Walsh *et al.*, that there may be a reason to try but there is no expectation of success, and that Beeler *et al.* do not say which antibodies to use.

Applicant's arguments have been fully considered and not found persuasive.

Applicant is arguing the references, in part, individually and that is not the basis of the rejection.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Beeler *et al.* teach that RSV is the most important cause of severe lower respiratory tract illness and that virus neutralizing/protection in vivo correlates with antibodies to the F protein (page 2941, first and second paragraphs). Beeler *et al.* teach specific neutralizing monoclonal antibodies (Table 1).

The argument of no reasonable expectation of success in making the antibodies is not persuasive because the examined claims are drawn to products, not to methods.

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The new limitations (adding functional requirements for protection) do not change the structure of the antibody but merely recite a property of the claimed antibody.

Applicant's argument of reasonable success is also not persuasive because the product is not an unexpected result but what is required of an antibody that has therapeutic value. One of ordinary skill in the art at the time of invention would have been motivated to make the claimed antibodies because the prior art teaches that anti-F RSV antibodies need to be neutralizing and that these correlate with protection as stated in Beeler *et al.* As pointed out by Applicant, Walsh *et al.* teach that there is a 2 of 8 antibody correlation between in vitro and in vivo neutralization. This indicates that one of skill in the art would know that the antibodies need to function in vivo and that screening is routine and would not be undue experimentation to determine the properties of the chimeric antibodies that meet the limitations of the claims.

The new limitations to the claims do not add any feature or structure that distinguish the claimed antibodies from the antibodies obvious over the prior art. The limitations merely point out properties an antibody would have that is therapeutically useful.

Thus, it would have been *prima facie* obvious to use the method of Jones *et al.* to make human-murine antibodies with the CDRs of Beeler *et al.* with the expectation of success in producing a human-murine neutralizing antibody against RSV which protects in against RSV infections in cotton rats and humans.

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Claims 35-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Queen *et al.* (US 5693762) in view of Beeler *et al.*

To clarify the statement in the previous action, Queen *et al.* do not teach the claimed antibodies but do teach how to make human-murine chimeric antibodies as acknowledged by applicant.

Applicant argues that Beeler *et al.* do not disclose or suggest to one of ordinary skill in the art human-murine antibodies of any sort, that Beeler *et al.* do not disclose which antibodies could be humanized and retain there neutralizing properties and be protective in animals. Citing Walsh *et al.* again as a discussed in the previous rejection, one of skill in the art would not know what antibodies would be protective in vivo.

Applicant argues concerning the commercial success and points out that there is a relationship between the product and its success and the claimed invention and that these features are in the claimed invention.

Applicant's arguments have been fully considered and not found persuasive.

First, the claims are rejected over a combination of references, not individual references.

Essentially as stated in the previous action, one of ordinary skill in the art would motivated to make human murine chimeric antibodies that are protective because anti-F antibodies are taught to be important by Beeler *et al.* Queen provides a method for making chimeric antibodies and Beeler *et al.* provides murine antibodies that are shown to be neutralizing. Knowing the skill in the art at the time of invention as taught by Queen, one of ordinary skill in the art would have the expectation of success in making

the claimed antibodies having the antibodies of Beeler *et al.* as starting material to make murine-human chimeric antibodies against RSV-F that are protective in animals.

One of ordinary skill in the art at the time of invention would know that the antibodies need to be protective in vivo to be useful as taught by Walsh *et al.* and additionally would know that it would be routine to screen for antibodies that have the properties of being protective in vivo.

Second, the exhibits are not supportive of the full scope of the presently claimed antibodies. The exhibits are not persuasive because they are drawn to one product and the claims are drawn to a genus, see MPEP 116.03(a).

Applicant's arguments that the success of the commercial product is related in some way to the properties of the product was not argued by the examiner. The points applicant argues are correct for the product disclosed by the exhibits but as stated above, the claims are drawn to a genus and the showing of success with one product is not commensurate in scope with the claimed invention. Furthermore, the choices made marketing and sales do not alter the patentability of a product.

One of ordinary skill in the art at the time of invention would have been motivated to make the claimed antibodies because the prior art teaches that anti-F RSV antibodies need to be neutralizing and that these correlate with protection as stated in Beeler *et al.* and Beeler *et al.* teaches such antibodies. As pointed out by Applicant, Walsh *et al.* teach that there is a 2 of 8 antibody correlation between in vitro and in vivo neutralization. This indicates that one of skill in the art would know that the antibodies

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need to function in vivo and that screening is routine and would not be undue experimentation to determine the properties of the chimeric antibodies that meet the limitations of the claims.

The new limitations to the claims do not add any feature or structure that distinguish the claimed antibodies from the antibodies obvious over the prior art. The limitations merely point out properties an antibody would have that is therapeutically useful.

Thus, it would have been prima facie obvious to use the method of Queen *et al.* with the CDRs of Beeler *et al.* with the expectation of success in producing a human-murine chimeric antibody against RSV-F which prevents infection in cotton rats and humans because Beeler *et al.* provide known neutralizing antibodies.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
2 February 2005



ALI R. SALIMI
PRIMA EXAMINER